UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.usplo.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/719,007	11/20/2003	Randolph Mellus Johnson	DURE-007CON2	9101	
	7590 06/28/2007 FIELD & FRANCIS LLP		EXAMINER		
1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			GHALI, I	GHALI, ISIS A D	
		•	ART UNIT	PAPER NUMBER	
			1615		
	٠,	•		•	
•	•		MAIL DATE	DELIVERY MODE	
		· .	06/28/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Advisory Action Before the Filing of an Appeal Brief

Application No.	Applicant(s)	
10/719,007	JOHNSON ET AL.	
Examiner	Art Unit	
Isis A. Ghali	1615	

zororo ano i anni dele ani zoror	Exammer	Art office				
	Isis A. Ghali	1615				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address						
THE REPLY FILED <u>07 June 2007</u> FAILS TO PLACE THIS APF			:			
1.  The reply was filed after a final rejection, but prior to or or this application, applicant must timely file one of the follow places the application in condition for allowance; (2) a Not a Request for Continued Examination (RCE) in compliant time periods:	wing replies: (1) an amendment, aff otice of Appeal (with appeal fee) in (	fidavit, or other evider compliance with 37 C	nce, which FR 41.31; or (3)			
a) The period for reply expiresmonths from the mailin						
b) The period for reply expires on: (1) the mailing date of this A no event, however, will the statutory period for reply expire I Examiner Note: If box 1 is checked, check either box (a) or TWO MONTHS OF THE FINAL REJECTION. See MPEP 7	ater than SIX MONTHS from the mailin (b). ONLY CHECK BOX (b) WHEN THI 06.07(f).	g date of the final rejecti E FIRST REPLY WAS F	ion. FILED WITHIN			
Extensions of time may be obtained under 37 CFR 1.136(a). The date have been filed is the date for purposes of determining the period of exunder 37 CFR 1.17(a) is calculated from: (1) the expiration date of the set forth in (b) above, if checked. Any reply received by the Office late may reduce any earned patent term adjustment. See 37 CFR 1.704(b)	on which the petition under 37 CFR 1.1 of tension and the corresponding amount shortened statutory period for reply origor than three months after the mailing date.	of the fee. The appropr inally set in the final Off	iate extension fee ice action; or (2) as			
NOTICE OF APPEAL	pliance with 37 CER 41 37 must be	filed within two mont	hs of the date of			
2. The Notice of Appeal was filed on A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).						
<u>AMENDMENTS</u>						
3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below);						
(b) They raise the issue of new matter (see NOTE below	DW);	ducina or simplifyina	the issues for			
(c) They are not deemed to place the application in be appeal; and/or			(He Issues IOI			
(d) They present additional claims without canceling a NOTE: (See 37 CFR 1.116 and 41.33(a)).		jected claims.				
4. The amendments are not in compliance with 37 CFR 1.1	21. See attached Notice of Non-Co	ompliant Amendment	(PTOL-324).			
5. Applicant's reply has overcome the following rejection(s):						
<ol> <li>Newly proposed or amended claim(s) would be a non-allowable claim(s).</li> </ol>	illowable if submitted in a separate,					
7. For purposes of appeal, the proposed amendment(s): a) how the new or amended claims would be rejected is protected. The status of the claim(s) is (or will be) as follows: Claim(s) allowed:	☐ will not be entered, or b) ☐ w ovided below or appended.	ill be entered and an	explanation of			
Claim(s) objected to: Claim(s) rejected:						
Claim(s) withdrawn from consideration:						
AFFIDAVIT OR OTHER EVIDENCE	0.00					
8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will <u>not</u> be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).						
9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).						
10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.						
REQUEST FOR RECONSIDERATION/OTHER  11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  See Continuation Sheet.						
12. Note the attached Information Disclosure Statement(s).  13. Other:	(PTO/SB/08) Paper No(s)		•			
			· <1.0			
	ISIS GHALI RIGIARY EXAMINER	Isis A Ghali Primary Examiner Art Unit: 1615	hisshol			
·	•					

Continuation of 11. does NOT place the application in condition for allowance because:

Applicants argue that no motivation to combine convective device that may operate via pump as Magruder's with polymeric matrix that operates by diffusion as Nelson's especially to deliver high potent drugs as fentanyl and sufentanil.

In response to this argument, it is argued that the invention as a whole is taught by the combined teachings of Magruder and Nelson. Magruder recognized highly loading of beneficial agents including analgesics and their delivery at a controlled rate continuously over time and over a broad range of dosage delivery rates according to predetermined time-release pattern. Nelson is relied upon for the teaching of fentanyl and sufentanil over extended period of time. The convective device disclosed by Magruder can deliver broad ranges of dosages, and one having ordinary skill in the art would have determined the dosages of potent fentanyl and sufentanil when delivered by convective devices. A conclusion of obviousness does not require absolute predictability, but reasonable expectation of success. In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. In re Preda, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

ISIS GHALI PRIMARY EXAMINER

ais Shal